# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

 $\mathbf{v}$ .

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company;

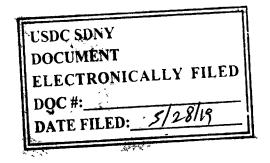
MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.; and

MICHAEL BEAMAN, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.

Defendants.

Case No. 1:17-cv-00124-LLS

JOINT REPORT PURSUANT TO FED. R. CIV. P. 26(f) AND PROPOSED SCHEDULING ORDER



Pursuant to Rule 26(f) of the Federal Rules of Civil Procedure and this Court's Order for Conference Pursuant to Rule 16(b) [Doc. No. 54], counsel for the above-captioned Plaintiffs and Defendants (collectively, the "Parties") met and conferred on May 17, 2019 and again on May 23, 2019 by telephone regarding the matters addressed below. The Plaintiffs request that the Court allow Part (3) below to serve as the proposed discovery plan and as the required joint scheduling order.

# (1) <u>Date of Conference and Appearance for the Parties:</u>

- a. Date and location of the conference: May 28, 2019 at 3 p.m. in Courtroom 21C.
- b. For Plaintiff, Federal Trade Commission:

Michelle Rusk

Annette Soberats

c. For Plaintiff, People of the State of New York by New York State Attorney General Letitia James:

Kate Matuschak

d. For Defendants, Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., d/b/a Sugar River Supplements, and Quincy Bioscience Manufacturing, LLC:

Geoffrey W. Castello

Glenn T. Graham

Kelley Drye & Warren, LLP

e. For Defendants, Michael Beaman and Mark Underwood (the "Individual Defendants"):

Michael B. de Leeuw

John B. Kelly

Cozen O'Connor

# (2) Concise Statement of Issues:

## Plaintiffs' Statement:

Plaintiffs the Federal Trade Commission (FTC) and the People of the State of New York, by the Attorney General of the State of New York (NYAG) brought this action to challenge

Defendants' conduct in connection with their marketing and sale of the dietary supplement "Prevagen" for purported memory and other cognitive benefits. The FTC brought this action under Section 13(b) of the Federal Trade Commission Act (FTC Act), 15 U.S.C. § 53(b), to obtain permanent injunctive relief and equitable monetary relief, alleging that Defendants' conduct was false and deceptive in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52. The NYAG charged that the same conduct constituted fraudulent or illegal acts in violation of New York Executive Law § 63 (12) as well as deceptive acts and false advertising in violation of New York General Business Law §§ 349 and 350. Specifically, Plaintiffs contend that Defendants' memory and cognition claims were false or unsubstantiated at the time they were made. Defendants' primary support for their claims is a human clinical study (the "Madison Memory Study") that failed to find any statistically significant benefit of Prevagen compared to a placebo, either for the study population as a whole, or for any sub-group population. In addition, Plaintiffs contend that Defendants' own testing disproves any plausible. mechanism of action to support a theory that the sole active ingredient in Prevagen, the dietary protein "apoaequorin," would have any effect on brain chemistry or brain function. As alleged in the Complaint, that testing shows that the protein is rapidly digested in the stomach like any other dietary protein and cannot reach or cross the blood brain barrier.

The Complaint names four corporate defendants and two individual defendants.

Plaintiffs allege that the corporate defendants operated as a common enterprise while engaged in the challenged practices and are thus jointly and severally liable. Plaintiffs further allege that the individual defendants, President Mark Underwood and CEO Michael Beaman, were actively involved in the companies' business affairs and making corporate policy, including the design and conduct of the research on Prevagen's efficacy and the creation and approval of the

challenged advertising. The Complaint alleges that, by virtue of the control over, authority to control, and active participation in that conduct, Underwood and Beaman are individually liable.

At the time Plaintiffs filed the Complaint in January 2017, Defendants were making false and deceptive claims in their extensive and ongoing national marketing campaign, through which Defendants promoted the sale of Prevagen to consumers at national retail outlets and online throughout the United States, including in New York, resulting in sales from 2007 through mid-2015 totaling \$165 million. Defendants continue to market and sell Prevagen nationwide, with the alleged false and deceptive claims appearing in national television ads airing daily on multiple networks. Plaintiffs seek permanent injunctive relief to halt and redress the challenged marketing, as well as appropriate ancillary relief, including consumer refunds and disgorgement of ill-gotten gains. In addition, Plaintiff NYAG seeks the award of civil penalties under state law.

Prior to and intermittently for a brief period after the filing of the Complaint, the Parties engaged in settlement discussions. It is Plaintiffs' view that the Parties remain far apart and that mediation is unlikely to be productive at this time.

The issues in this case are: (1) whether the advertising, marketing, and labeling of Prevagen conveyed the challenged claims about memory and other cognitive benefits; (2) whether, at the time those claims were made, Defendants' failed to possess competent and reliable scientific evidence substantiating those claims with the result that the claims are false and deceptive in violation of FTC and New York law; (3) whether the corporate defendants operated as a common enterprise and are thus jointly and severally liable; (4) whether individual defendants Underwood and Beaman are individually liable; (5) the appropriate scope and nature of permanent injunctive relief; (6) the appropriate amount of ancillary monetary relief, including

consumer redress and disgorgement; and (7) the calculation of civil penalties under New York law.

Plaintiffs reassert their position – already fully briefed – that any arguments for dismissal not previously addressed by this Court or by the Second Circuit are without merit. Specifically: (1) this Court has personal jurisdiction over the individual defendants, as long as they had minimum contacts with the country as a whole, under FTC Act Section 13(b)'s authorization of nationwide service (15 U.S.C. § 53(b)) (and the Court also has personal jurisdiction under New York CPLR § 302(1)(1)); (2) the Complaint sets out a detailed factual basis sufficient to show that both Individual Defendants participated in, controlled, and either knew of or recklessly disregarded the deceptive conduct; (3) the First Amendment provides no protection to any advertising claims that the Court determines at trial to be deceptive; and (4) under even the most restrictive interpretations of FTC Law and common law, the FTC had a valid quorum when the three sitting Commissioners voted to issue the Complaint (two "yes" votes and one "not participating").

#### **Defendants' Statement:**

Defendants dispute nearly all of Plaintiffs' factual assertions above and deny the material allegations of the Complaint. As set forth in the motion to dismiss, Defendants state that all of the advertising statements with respect to the dietary supplement Prevagen are fully substantiated by competent and reliable scientific evidence including, but not limited to, the Madison Memory Study. Defendants further state that all of the advertising for Prevagen complies with the FTC's advertising guidance for dietary supplements and applicable law. Accordingly, Plaintiffs' Complaint fails to state a claim for relief and should be dismissed because Defendants'

statements about Prevagen's efficacy are true and fully substantiated. Defendants deny that Plaintiffs are entitled to any of the relief they seek.

In its September 28, 2017, Opinion and Order dismissing the complaint, the Court reached only Quincy's argument that the Complaint failed to state a claim for violation of the FTC Act pursuant to Fed. R. Civ. P. 12(b)(6). The Court declined to exercise supplemental jurisdiction over the New York state law claims and concluded that, "[a]Il claims being dismissed, there is no need to consider the defendants' remaining arguments, or the [Individual Defendants'] motion denying jurisdiction." (Dkt. #45 at 13.) The Second Circuit reversed, and expressly noted "that Defendants-Appellees have raised several grounds for affirmance that the district court did not consider. We express no opinion on these arguments, and the district court may consider them in the first instance on remand." (Dkt. #50 at 4.) Defendants submit that these threshold issues should be decided by this Court based on the Motion to Dismiss briefing prior to the parties engaging in any discovery. The Parties are willing to provide supplemental briefing if the Court believes it would be helpful.

Specifically, the Individual Defendants argued in their April 6, 2017 Motion to Dismiss that they are not subject to personal jurisdiction in this Court. The Individual Defendants do not have any relevant relationship to New York. And the FTC Act does not automatically allow for personal jurisdiction simply because there is an allowance for nationwide service of process.

The Individual Defendants also moved to dismiss under Fed. R. Civ. P. 12(b)(6), arguing that the Complaint does not adequately allege the Individual Defendants' involvement in the marketing practices at issue. These issues have not yet been decided by this Court or by the Second Circuit.

Likewise, no court has ruled on the arguments in Quincy's Motion to Dismiss that this action amounts to an unconstitutional restraint on commercial speech and that FTC lacked a valid quorum to bring this action and thus it is *ultra vires*.

Defendants submit that Plaintiffs' characterization of the prospect of settlement is premature. On June 12, 2019, Quincy's counsel will meet with the Director of the FTC's Bureau of Consumer Protection, Andrew Smith, as well as other FTC representatives, to discuss the matter and present the company's settlement position.

#### (3) Discovery Plan and Case Schedule:

## Plaintiffs' Statement re Discovery Plan:

The case is moderately complex. It involves two plaintiffs, four corporate defendants, and two individual defendants and includes charges under both Federal and New York State laws. The case will require significant discovery given the extensive, multi-platform advertising and marketing campaign and the disputed-scientific evidence regarding Prevagen's efficacy and purported mechanism of action. Plaintiffs intend to conduct discovery on subjects relevant to the allegations in this action and the relief sought, including injunctive and equitable monetary relief, as well as defenses raised in Defendants' Answer. For example, Plaintiffs will seek discovery on the content and dissemination of the challenged advertising, labeling, and other marketing materials; the planning, conduct, and analysis of data on which Defendants rely to substantiate challenged claims; the extent of consumer injury; and the extent of profits Defendants obtained as a result of the illegal conduct. Plaintiffs anticipate that discovery will include relevant third parties.

# Defendants' Statement re Discovery Plan:

Defendants will seek discovery concerning the allegations of the Complaint and Defendants' defenses thereto, if the Complaint survives dismissal.

# Joint Statement re Discovery Plan:

The information set out below reflects all Parties' agreement as to discovery scheduling and other aspects of the discovery plan, including the following:

- a. Fact Witness Depositions: The Parties agree that they are not in a position to identify all witnesses that they may seek to depose at this time, as Defendants have not yet filed an Answer and the parties have not yet exchanged initial disclosures. The Parties agree, therefore, that each party may seek to depose additional fact witnesses, other than those named below, prior to completion of fact discovery. At this time, the Parties do not anticipate exceeding ten (10) fact witness depositions total for Plaintiffs and ten (10) fact witness depositions total for Defendants. This does not include deposition of expert witnesses. If additional depositions are needed, the Parties will meet and confer on seeking leave from the Court through joint stipulation. Plaintiffs currently intend to seek the deposition of the following individuals and entities:
  - 1. Michael Beaman;
  - 2. Mark Underwood;
  - 3. Kenneth C. Lerner;
  - 4. Dakota Miller;
  - 5. Todd Olson;

- 6. A Rule 30(b)(6) witness from the Quincy corporate defendants on topics identified through discovery;
- A witness involved in the reanalysis of Defendants' Madison Memory Study by Georgetown Economic Services;
- One or more witnesses from third-party advertising or marketing firms on the topic of the creation of Defendants' television ads and marketing materials;
   and
- 9. An individual witness or a Rule 30(b)(6) witness from the Food and Drug Administration on topics identified through discovery.

Defendants currently intend to seek the deposition of the following individuals and entities:

- 1. One or more Rule 30(b)(6) witness from the Federal Trade Commission on topics identified during discovery;
- 2. One or more Rule 30(b)(6) witness from the Food and Drug Administration on topics identified during discovery and any communications between FTC and FDA regarding the subject matter of this action.
- One or more Rule 30(b)(6) witness from the New York Attorney General's
   Office on topics identified during discovery;
- 4. Any fact witnesses identified by Plaintiffs during discovery; and
- 5. Any and all persons identified by Plaintiffs and/or any third-parties identified during discovery.
- b. <u>Case Schedule</u>: The Parties agree to complete fact discovery first, after which they will conduct expert discovery. Completing fact discovery first will establish the

factual basis upon which the experts will then form their opinions as to whether the challenged claims are substantiated.

# Plaintiffs' Proposed Case Schedule:

- Rule 26(f) Conference: The Parties held their Rule 26(f) conference on May
   and conferred again on May 23, 2019.
- Rule 26(a)(1) Disclosures: The Parties will exchange Initial Disclosures on June 12, 2019. The Parties will supplement those initial disclosures as warranted in a timely manner.
- 3. E-discovery: The Parties anticipate that the claims and defenses will involve electronically stored information (ESI). The Parties continue to discuss topics related to e-discovery, including: production of ESI according to an agreed-upon protocol; litigation hold for electronically stored information (ESI) and hard copy material; costs of preservation and production; and any inadvertent production of privileged information. The parties will meet and confer on these topics by June 28, 2019.

## 4. Production of Documents:

- Initial document requests by the Parties will be served on or before July 15, 2019.
- Supplemental document requests will be served no later than February 14, 2020.
- 5. Written Discovery: Interrogatories and requests for admission by all Parties will be served no later than February 14, 2020. Plaintiffs request that there be no numerical limits on requests for admissions or, if the Court imposes a limit,

that the use of such requests not be required to authenticate the genuineness of described documents and that the Parties be directed to use good faith efforts to stipulate as to genuineness. Defendants request that requests for admission be limited to no more than one-hundred (100) in total. The parties agree that each side will not serve more than twenty-five (25) interrogatories in total.

- Fact Witness Depositions: All fact witness depositions will be completed by March 16, 2020.
- 7. <u>Fact Discovery Completed</u>: All fact discovery will be completed by March 16, 2020.
- 8. Expert Reports and Depositions:
  - i. The Parties will exchange expert reports no later than April 30, 2020.
  - The Parties will exchange rebuttal expert reports no later than May 29, 2020.
  - iii. The Parties will complete expert discovery, including expert depositions, by June 30, 2020.

#### O. Dissesitive Metions

- i. Dispositive motions will be due no fater than August 11, 2020.
- ii. Response to dispositive motions will be within 30 days after dispositive motions are filed.

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- iii. Replies to responses will be due within 14 days after responses to
  - dispositive inotions are filed.
- Exchange of Pre-Trial Order Materials: The Parties will exchange pre-trial order materials no later than November 15, 2020.

- 11. Pre-Trial Order and Trial Briefs: The Parties will submit a pre-trial order in a form conforming with the Court's instructions together with trial briefs and proposed findings of fact and conclusions of law no later than January 15, 2021.
- 12. <u>Final Pre-Trial Conference</u>: A final pre-trial conference pursuant to Fed. R.
  Civ. P. 16(e) will take place on \_\_\_\_\_\_\_.
  13. <u>Trial</u>: <u>Trial</u> will commence on \_\_\_\_\_\_.

Plaintiffs believe that their proposed schedule is appropriate and in the interest of the efficient administration of justice. Defendants' remaining grounds for dismissal are insufficient bases to warrant delay of this action.

# **Defendants' Proposed Case Schedule:**

Detendants believe the Court should decide the additional grounds for dismissal set forth in their Motions to Dismiss. These bases have not yet been addressed by this Court or the Second Circuit. Defendants respectfully request that discovery be stayed during the pendency of those motions. As noted, the remaining issues to be decided include (1) the threshold issue of personal jurisdiction over the Individual Defendants, (ii) whether Plaintiffs adequately stated a claim against the Individual Defendants; (iii) whether this action amounts to an unconstitutional restraint on commercial speech; and (iv) whether the FTC lacked a valid quorum to bring this action and thus is *ultra vires*. Defendants do not oppose the time intervals in Plaintiffs' proposed schedule but believe that the dates should commence—if ever—from the time the Court rules on the additional grounds for dismissal, with the Rule 26(a)(1) Disclosures and initial documents requests to be due within thirty (30) days of the Court's decision and all subsequent deadlines be adjusted actoringly.

- (4) <u>Limitations on Discovery</u>: The Parties are not proposing limitations on discovery at this time.
- (5) <u>Disputed Discovery Issues</u>: There are currently no disputed discovery issues.

## (6) Anticipated Expert Testimony:

Subject to possible revision based on Defendants' answer and discovery, Plaintiffs currently anticipate calling upon experts in the following four fields: 1) memory, cognition and clinical study design related to those research fields; 2) statistical analysis of clinical research; 3) pharmacology and biochemistry; and 4) forensic accounting and monetary relief.

Defendants anticipate calling upon experts in the fields identified by Plaintiffs and in any additional fields as may be identified in the course of discovery. Defendants also anticipate calling an expert in the field of administrative practice.

- (7) Anticipated Length of Trial: The Parties currently anticipate a ten-day trial. It is

  Plaintiffs' position that this matter should proceed as a bench trial because this case is

  fundamentally about equitable relief and Defendants are therefore not entitled to a jury

  trial. Defendants submit they are entitled to a jury trial.
- (8) This [Proposed] Scheduling Order may be altered or amended only on a showing of good cause not foreseeable at the time of the Parties' May 28, 2019 conference with the Court or when justice so requires. The Parties agree that within two weeks after Defendants file an Answer in this matter, the Parties may seek to amend the discovery dates and scope of this [Proposed] Scheduling Order to respond to issues raised in the Answer.

Dated: May 24, 2019

FEDERAL TRADE COMMISSION

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SO ORDERED

Hon. Louis L. Stanton

Hon. Louis L. Stanton
United States District Judge

Dated:

May 28, 2019